4 CONCLUSIONS

- McNeil believes that the current labeling for OTC ibuprofen products is appropriate for safe consumer use. We also recognize that FDA has been implementing OTC labeling modifications that provide more specific language related to organ systems, disease states, and symptoms. As such, McNeil is committed to adopting the specific format and language of warnings proposed by FDA provided that the warnings have a sound scientific basis.

- McNeil can support adoption of a general stomach bleeding label warning on OTC ibuprofen and all other OTC Analgesic NSAIDs because GI toxicity including stomach bleeding is noted to occur at recommended doses. It has been suggested that a stomach bleeding warning may be duplicative of language included in the OTC Analgesic NSAID alcohol warning. However, stomach bleeding can occur with use of OTC NSAIDs independent of alcohol use by history. McNeil can support both warnings because each different label warning helps address a public health issue for two different at risk populations.

- So as to improve consumer awareness of NSAID active ingredients, McNeil supports replacing the current approved OTC ibuprofen label warning, "talk to a doctor or pharmacist before using an ibuprofen product if you are already taking any other product that contains ibuprofen or any other pain reliever/fever reducer." with a new warning, "Do not use • with any other product containing ibuprofen or other NSAIDs such as aspirin, ketoprofen, or naproxen sodium.

    - So as to ensure appropriate and consistent consumer labeling, McNeil recommends that FDA require similar labeling changes for aspirin-containing products and for all other OTC NSAID products.

- McNeil believes that an alcohol warning is appropriate for OTC ibuprofen and all other OTC NSAIDs, as required by Final Rule dated October 23, 1998 and included in the Proposed Rule to amend the TFM dated August 21, 2002. The scientific evidence and public health issues related to the need for an alcohol warning on all OTC IAAA drug products, including ibuprofen, have previously been more than fully evaluated by FDA and expert members of FDA Advisory Committees.

- Recently published data are consistent with previous scientific evidence and continue to demonstrate an increase in risk of GI complications with the use of alcohol and OTC NSAIDs, including ibuprofen. Wyeth's published literature update does nothing to change the GI risk assessments.

- It is appropriate to retain the alcohol warning as it exists and to adopt a separate general stomach bleeding label warning for OTC ibuprofen because each of these warnings would be directed to two different at risk populations.

- If the alcohol warning was removed from OTC ibuprofen, it might lead consumers to conclude they should select ibuprofen as the only safe analgesic choice if they consume alcohol.

- Should FDA wish to re-consider the alcohol warning, this should only occur under a formal rule making process with advance notice and full open public discussion, including a comprehensive review of all scientific data for all OTC IAAA ingredients.